REMARKS

Independent claim 1 and claims 2-9 depended therefrom remain in this application for examination.

The Examiner has suggested guidelines for the arrangement for the specification to which guidelines suggest but not require section headings in bold type. Applicants are aware of situations in which section identification has been used adversely with respect to a patentee's interest. Accordingly, Applicants prefer not to use section headings. However, since the Examiner in all likelihood will put these headings in anyway, by Examiner's Amendment, Applicants have complied with the Examiner's suggestion.

Rejections to the Application (by Office Action paragraph number):

1. Applicants have now described each figure and subfigure of the drawings by identifying Fig. 2A and Fig. 2B and by identifying Fig. 4A, 4B and 4C.

2. At page, 19, line 16, Applicant has inserted "Fig. 1."

Claim Rejections Under 35 U.S.C. §112, second paragraph (by Office Action paragraph number):

4. Applicants have amended claims 1-5 so as to be definite under 35 U.S.C. §112.

5. With respect to claim 1, Applicants have amended claim 1 to define the channel section as follows:

> "a sample channel section in the flow through unit for receiving the sample, the sample channel section having two ends both of which have at least one fluidic connection to determine therebetween a volume in the sample channel section, which volume defines the volume of a sample to be analyzed."

6. The Examiner initially finds the meaning of the term "fluidic connections" in claim 1 unclear because it is unclear how a pump reads on the broadest reasonable interpretation of the term "fluidic connection." Applicants respectfully submit that the fluidic connections are defined by "outlets or inlets to peristalic pumps, syringes or syringe pumps." The Examiner's attention is directed to the description of the term fluidic connection at page 25, line 33 through page 26, line 7 which recites in part:

> . . . the fluidic connections are not integrated into the flow through unit, but are connected to the flow through unit for use externally, that is to say from the adapter chamber. In this manner, in the flow through unit only appropriate openings need to be provided, which in particular for flow though units which are replaced after use, is considerably less expensive than the inclusion of expensive valves, etc."

Applicants define channel sections having openings at two ends which determine therebetween a volume in the channel defining the volume of a sample to be analyzed.

7. In claim 2, Applicants have deleted the term "essentially consisting of" and inserted the term "comprises."

8. Claims 4 and 5 have been amended to recite specific structures rather than reciting general uses of structure.

9. By reciting specific structure, Applicants' claims 4 and 5 are now set forth as apparatus claims properly depended from apparatus claim 1.

Claim Rejections Under 35 U.S.C. §102:

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. §102(b) as being anticipated by Chow et al. '402. Applicants respectfully traverse this invention.

A clear distinction between Applicants' claimed invention and Chow '402 is that Chow is directed to a "continuous flow unit." The term "continuous flow unit" in this application is derived from an inappropriate English translation of the German word "Durchflubeinhet." In light of

Applicant's specification, which is clearly directed to a "flow through unit" it is clear that the term "continuous" is under an ordinary meaning misdiscriptive of Applicant's claimed analytical unit.

It is respectfully submitted that the terminology "flow through" is not new matter not only because the specification does not support "continuous flow," but also because the Abstract of the Disclosure uses the terminology "through flow," which supports the amendment to "flow through."

In Applicants' claimed analytical unit, the flow through unit 1 is best shown in Fig. 6 and is schematically illustrated and explained with respect to Figs. 1, 2A, 2B and 3 does not utilize continuous flow. Rather, the flow is discontinuous because as is clear from the discussion at page 20, line 33 through page 22, line 25 that the flow is not continuous. Specifically, at page 21, lines 12 and 15, Applicant's recite:

> . . . at the completion of the filling operation, the fluidic connections are closed. In this manner a close system is obtained without hydrodynamic flow, in which the separation can be carried out reproducibly.

With respect to the "filling operation" is the operation described at page 21, lines 32-35 where it is recited that:

> Figure 2B shows how the sample is introduced into the channel section K1 and the channel section K2 is filled via R3 with a leading buffer.

It is further recited how precise filling is accomplished as follows on page 21, lines 5-8:

> By pumping leading buffer and the sample volume simultaneously against one another a particularly precise filling of the channel sections K1 and K2 is achieved.

Accordingly, once the precise filling of channel section K1 is achieved, the fluidic connections (F1-F6) are closed. It is respectfully submitted that it is clearly established from the specification that while fluid can flow through the system, the flow is not continuous. Therefore, amending the

specification to correspond to the description, so that the term "continuous" is not utilized to describe the flow, is justified and proper.

With respect to Chow et al. '402, Chow et al. is directed to a different type of system wherein continuous flow is utilized rather than a system in which a sample of a pre-determined volume is prepared. More specifically, in Applicants claim 1, the channel section is recited as the element which defines the volume of a sample to be analyzed and is set forth as follows:

> "A channel section for receiving the sample of pre-determined volume, the channel section having openings at two ends thereof both of which have at least one fluidic connection to determine therebetween a volume in the channel, which defines the pre-determined volume of the sample to be analyzed."

As is set forth in the specification, the fluidic connections are open to admit the fluid from which the sample is obtained and closed upon being filled by the sample. Since there are buffer solutions in the channel system at both ends of the channel, the volume of the sample is pre-determined. There is no such disclosure in Chow et al. '402, rather in Chow et al, the fluid flows continuously through the channels during analysis.

Applicant's invention is directed to analysis situations where it is important to know the exact volume of the sample introduced into the analytical system. Due to the relatively small dimensions of such systems, there are no suitable possibilities for delivering sample volumes which are incorporated in configuration. Chow et al. does not address this problem addressed by Applicants. The system of Chow et al. is designed only for applications in which the exact volume of the sample is irrelevant or for electro-kinetic injection which only two crossing channels with electrodes at each end are necessary. This is readily apparent from the Figures of Chow et al. in which all the figures show flow through units having open ports for sample delivery.

Note in column 6, lines 40-51 of Chow et al., it is recited that the holes 24 of Fig. 2A functions as reservoirs as well as providing ports. Moreover, in column 6, lines 56-67 it is recited

that the device is often including multiple introduction ports in reservoirs which might be coupled to sample introduction systems. Consequently, Chow et al. uses a totally different sample delivery system.

The term "fluidic connections" which is discussed in Applicant's specification at page 25, line 33 to page 26, line 7, are connections which in general provide a connection means for delivering and removing fluids from outside of the channels system and vice-versa. In Chow et al., the paragraph bridging columns 7 and 8 cited by the Examiner is not concerned with liquid connections, but with electro-kinetic material transport (see column 7, line 52.) Electro-kinetic material transport is unsuitable for moving a "volume" of sample fluid because it always additionally changes the composition of a sample that has already separated. Note, new claims 8 and 9 that the sample volume is more than 0.1μl which is substantially greater than the volume of sample separated by electro-kinetic transport.

Applicants' are claiming an analytical unit (see Fig. 6) having fluidic connections such as 8a, 8b and 8c. In general, fluidic connections in the context of this application provide connections for delivering and removing fluids from outside the channel system into the channel system and vice-versa. The paragraph bridging columns 7 and 8 of Chow et al. cited by the Examiner there is no discussion of liquid connections, but rather a discussion of electro-kinetic material transport (see column 7, line 52). Clearly, there is no disclosure in Chow et al. '402 of the jist of Applicants invention which is to have a channel section with fluidic connections at both ends to define a sample volume. This difference is clear upon reviewing Chow et al.'s '402 Figure 2A wherein electrodes 204 penetrate the openings 24. There is no disclosure of structure that opens and closes the openings so that a selected volume is defined in the micro-fluidic device of Chow et al.

Claim Rejections Under 35 U.S.C.§103:

Claim 3 or claims 1-5 in the alternative are rejected under 35 U.S.C.§103(a) as being unpatentable over Chow et al. '402 in view of Blankenstein et al. Applicants respectfully traverse

this rejection.

This application currently names two inventors and Applicants affirm that the subject matter of the various claims was commonly owned at the time the inventions covered therein were made.

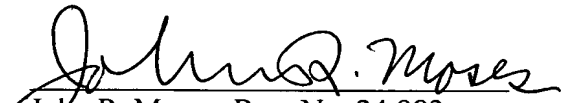
With respect to claim 3, the Examiner attempts to cure the deficiencies of Chow et al. as a reference against Applicant's claims by combining Chow et al. with Blankenstein et al. It is respectfully submitted that Blankenstein et al. does not disclose the concept of using a sample channel section to define a volume of a sample to be analyzed. As discussed with respect to the rejection under 35 U.S.C. §102, the application of defined sample volumes to miniaturized analytic units in the prior art very complicated. It is possible to use very expensive external dosage system or systems that do not require the application of defined sampled volumes such as Chow et al., but neither of these approaches solves the problem of providing an analytical unit utilizing a very simple technique to provide defined sample volumes. In accordance with Applicants' claimed invention, all that is needed is at least one sample receiving channel section with fluidic connections. The fluidic connection may be by any means suitable for charging or removing fluids. Moreover, the analytical unit and the fluidic connections therein need not be configured to include a dosage system. This is because dosing is preformed by the volume of the sample channel section K1 of the flow through unit exemplified in Figs. 2A and 2B.

In that this is a full and complete response to the Office Action of December 2, 2003, this application is now in condition for allowance and allowance is hereby respectfully requested.

If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



John R. Moses, Reg. No. 24,983
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-2335
Date: June 2, 2004